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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/971,902	10/05/2001	Peter R. Oeltgen	ZYM/09US	4028

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EXAMINER	
HAMUD, FOZIA M	
ART UNIT	PAPER NUMBER
1647	7

DATE MAILED: 09/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File cop 7

Offic Action Summary	Application No.	Applicant(s)	
	09/971,902	OELTGEN ET AL.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Receipt of Applicant's arguments and amendment, filed on 27 June 2003 in Paper No.6, is acknowledged. Claims 1, 8 and 10 have been amended. Claims 1-11 are pending and under consideration.

2. The following previous objection is withdrawn in light of Applicants amendments filed in Paper No.6, 06/27/03:

(I) The rejection of claims 1-11, made under 35 U.S.C. 112, second paragraph, is withdrawn.

Response to Applicants' Arguments and Amendment:

IDS:

3. Reference A.L, cited on the PTO form 1449, submitted by Applicants on 20 February 2002, has been considered.

Claim Rejections - 35 U.S.C. § 112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4a. Claims 1-11 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record, set forth in the office action mailed on 08 April 2003 in Paper No:5, pages 2-5.

Applicants argue that instant specification fully enables the inventive method for modulating or treating hepatic injury response by administering the peptide having SEQ ID NO:1, and therefore, meets the standard for enablement, because a person skilled in the art would be enabled to practice the invention commensurate in scope wit the

claims. Applicants argue that they disclose which compounds to administer, how to administer them, and under what clinical conditions to administer them and when to stop said treatment. With respect to which cytokines or cytokine cascade steps are to be modulated by compound D, Applicants argue that instant invention is directed to modulating cytokine hepatic injury response, not identification of the cytokine and/or cytokine cascade steps. Applicants conclude that there is no undue experimentation with respect to which cytokine the peptide of the instant invention modulates, because these considerations are not necessary to practice the full scope of the claimed method.

These arguments have been fully considered but are not found persuasive. With respect to Applicants' first argument, the instant specification is totally non-enabling for the claimed method and the skilled artisan would not be able to practice this method, because the specification establishes no nexus between the peptide of SEQ ID NO:1 and hepatic injury. Although the instant specification teaches which compound to administer, under what clinical conditions to administer it and when to stop said treatment, it provides no reason as to why this peptide would decrease cytokine mediated hepatic injury response or be effective in treating hepatic injury. Instant specification discloses no examples that demonstrate the administration of said peptide to a mammal was effective in treating hepatic injury or was effective in decreasing cytokine mediated hepatic injury response. Although working examples are not required under 35 U.S.C §112, first paragraph, they are one of the factors that must be considered when determining enablement, especially in light of the lack of guidance in the specification and the nature of the invention, since prior art is relatively silent to the

instantly claimed method of treating hepatic injury or decreasing cytokine mediated hepatic injury response by administering the peptide of SEQ ID NO:1. Any compound can be administered to a mammal suffering from hepatic injury, however there has to be sound scientific reasoning as to why the compound would be effective in said treatment. Furthermore, proper controls must be done addressing whether there are any undesirable side effects.

Applicants' argument that it is not necessary to identify which cytokines that the peptide of SEQ ID NO:1 modulates to practice instantly claimed method, is not persuasive, because not all cytokines are pro-inflammatory or cause hepatic injury. Therefore, the skilled artisan must know the responses of which cytokines to decrease. Thus, it will be undue experimentation to figure out which cytokines does the peptide of SEQ ID NO:1 modulate, how these cytokines are modulated, and to test if this peptide is effective in decreasing cytokine mediated hepatic injury response. In conclusion, Applicants provide no guidance regarding the use of the peptide of SEQ ID NO:1 in the claimed method. Applicants merely state that the peptide of SEQ ID NO:1 is used to treat hepatic or to decrease cytokine mediated hepatic injury response, but provide no evidence that this peptide can be effective *in vivo* or *in vitro* to treat hepatic injury.

Therefore, claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention.

N w Objections and Rejections:

Claim obj ctions

5. Claims 1-11 are objected to because of the following informalities:

5a. Claims 1, 8 and 10 are objected to because the claims recite "....administering SEQ ID NO:1...", however, since SEQ ID NO:1 is used to identify the peptide disclosed on page 2, lines 7-8 of the instant specification, it is recommended to recite "... administering the peptide consisting the amino acid sequence set forth in SEQ ID NO:1...".

Claims 2-7, 9 and 11 are objected to in so far as they depend on claims 1, 8 and 10.

Claim Rejections - 35 U.S.C. § 112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6a. Claims 1, 8 and 10 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the claims are directed to a method of decreasing a cytokine mediated hepatic injury response in a mammal (claim 1), a method of treating hepatic injury (claims 8 and 10), however, the claims do not recite a result step. Neither do the claims recite duration, (how long should said

administration continue) or the dosage of the peptide. Appropriate correction is required.

Claims 2-7, 9 and 11 are indefinite so far as they depend on claims 1, 8 or 10 for the limitations set forth directly above

Conclusion:

7. No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursday, 6:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary L Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Fozia Hamud
Patent Examiner
Art Unit 1647
12 September 2003